DK0400451

PCT

REC'D 14 JUL 2005

INTERNATIONAL PRELIMINARY REPORT ON PAPENTARESTY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

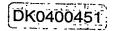
Total Part To	Applicant's or agent's file reference	FOR FURTUER A		
PCTDK2004000451	15450PCT00	FOR FURTHER AC	STION	See Form PCT/IPEA/416
PCTDK2004000451	International application No.	International filing date	(day/month/vear)	Priority date (day/month/year)
Applicant PPHARMEXA AS et al. 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 8 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. sent to the applicant and to the International Bureauy a total of sheets, as follows: sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. sent to the International Bureau only) a total of (indicate type and number of electronic carrier(e)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). 4. This report contains indications relating to the following items: Box No. Basis of the opinion Box No. V Lack of unity of invention Box No. V Lack of unity of invention Box No. V Leck of unity of invention Box No. V Leck of unity of invention Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement Box No. V Certain detects in the international application Box No. V Certain documents cited Box No. V Certain detects in the international application Box Holling address of the international preliminary examining authority: Certain defects in the international preliminary examining authority: Certain defects in the int	PCT/DK2004/000451		, ,,	1 7 7
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as Editor	Fax: +31 /0 340 - 3016		Telephone No. +31 70 34	10-4494

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/DK2004/000451

	Box No. I Basis of the report					
1.	With regard to the language, this filed, unless otherwise indicated	Vith regard to the language , this report is based on the international application in the language in which it was led, unless otherwise indicated under this item.				
	which is the language of a tr ☐ international search (und ☐ publication of the interna	slations from the original language into the following language, ranslation furnished for the purposes of: ler Rules 12.3 and 23.1(b)) tional application (under Rule 12.4) examination (under Rules 55.2 and/or 55.3)				
2.	With regard to the elements* of the international application, this report is based on <i>(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):</i>					
	Description, Pages					
	1-37	as originally filed				
	Sequence listings part of the desc	cription, Pages				
	1-10	as originally filed				
	Claims, Numbers					
	1-48	as originally filed				
	Drawings, Sheets					
	1/4-4/4	as originally filed				
	☐ a sequence listing and/or an	y related table(s) - see Supplemental Box Relating to Sequence Listing				
3.	☐ The amendments have result the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/figs ☐ the sequence listing (special any table(s) related to set	ecify):				
4.	Supplemental Box (Rule 70.2(c)) the description, pages the claims, Nos. the drawings, sheets/figs the sequence listing (spe	ecify): equence listing (specify):				
	* If item 4 applies, so	ome or all of these sheets may be marked "superseded."				

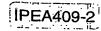


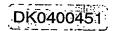


INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/DK2004/000451

	Par	k No. II	Priority		
_			Priority		
1.		prescrit	sea time nimit the reques	stea:	if no priority had been claimed due to the failure to furnish within the
		□ copy	\prime of the earlier application	n wh	nose priority has been claimed (Rule 66.7(a)).
		□ trans	slation of the earlier app	olicati	ion whose priority has been claimed (Rule 66.7(b)).
2.		been lo	oort has been establishe und invalid (Rule 64.1). s considered to be the r	i nus	if no priority had been claimed due to the fact that the priority claim has s for the purposes of this report, the international filing date indicated ant date.
3.	Ado	litional o	bservations, if necessar	y :	
	see	separa	te sheet		
_	Per	- No. III	Non catalillahmant		
		k No. III licabilit	Non-establishment (от ор	inion with regard to novelty, inventive step and industrial
1.	The obv	questio ious), or	ns whether the claimed to be industrially applic	inve able	ntion appears to be novel, to involve an inventive step (to be non-have not been examined in respect of:
		the enti	re international applicat	ion,	
	Ø	claims I	Nos. 47, 48 (with respec	ct to i	industrial applicability)
		because	e:		
	×	the said relate to (specify	o ine ioliowing subject n	n, or natte	the said claims Nos. 47, 48 (with respect to industrial applicability) r which does not require an international preliminary examination
		see sep	parate sheet		
		the des	cription, claims or drawi meaningful opinion cou	ings i	(indicate particular elements below) or said claims Nos. are so unclear formed (specify):
		the clair	ms, or said claims Nos. e formed.	are s	so inadequately supported by the description that no meaningful opinion
		no inter	national search report h	as b	een established for the said claims Nos.
		the nuc C of the	leotide and/or amino ac Administrative Instruct	id se ions	quence listing does not comply with the standard provided for in Annex in that:
		the writt	ten form		has not been furnished
					does not comply with the standard
		the com	puter readable form		has not been furnished
					does not comply with the standard
		the table	es related to the nucleo oply with the technical re	tide a equire	and/or amino acid sequence listing, if in computer readable form only, do ements provided for in Annex C-bis of the Administrative Instructions.
		See sep	parate sheet for further	detai	ls





INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/DK2004/000451

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1-48

No: Claims

Inventive step (IS)

Yes: Claims No: Claims

1-48

Industrial applicability (IA)

Yes: Claims

1-46

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet



DK0400451

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/DK2004/000451

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_		-	emental Box relating to Sequence Listing						
Co	ontii	านล	tion of Box I, item 2:						
1.	Wit	h re ess	regard to any nucleotide and/or amino acid sequence disclosed in the international application and essary to the claimed invention, this report has been established on the basis of:						
	a. type of material:								
		Ø	a sequence listing						
			table(s) related to the sequence listing						
	b. f	orm	at of material:						
		Ø	in written format						
		Ø	in computer readable form						
	c. t	ime	of filing/furnishing:						
		×	contained in the international application as filed						
		×	filed together with the international application in computer readable form						
			furnished subsequently to this Authority for the purposes of search and/or examination						
	!		received by this Authority as an amendment on						
2.		tne ad	addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating ereto has been filed or furnished, the required statements that the information in the subsequent or ditional copies is identical to that in the application as filed or does not go beyond the application as filed, appropriate, were furnished.						
3.	. Additional observations, if necessary:								

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Re Item II Priority

The claimed priority date is valid.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The subject matter of claims 47, 48 is directed to methods for treatment of the human or animal body by surgery or therapy and/or diagnostic methods practised on the human or animal body. For the assessment on the question as to whether this subject matter is industrially applicable, no unified criteria exist in the PCT Contracting States. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT, Rule 67.1(iv)).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents are referred to in this communication:

- D1: LAROCHE-TRAINEAU J ET AL: "Three-step purification of bacterially expressed human single-chain Fv antibodies for clinical applications" JOURNAL OF CHROMATOGRAPHY. BIOMEDICAL APPLICATIONS, ELSEVIER, AMSTERDAM, NL, vol. 737, no. 1-2, January 2000 (2000-01), pages 107-117, XP004184259 ISSN: 0378-4347
- D2: WO 97/24438 A (LAUS REINER; WU HONGYU (US); RUEGG CURTIS L (US); ACTIVATED CELL THER) 10 July 1997 (1997-07-10)
- 2. a) Document D1, which is considered to represent the most relevant state of the

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art, discloses (abstract; sections 2.3.4-2.3.6; page 116, left column, lines 1-3) a method for the purification of a recombinant protein comprising dialysis, metal affinity chromatography, size exclusion chromatography, anion exchange chromatography. From this, the subject-matter of claim 1 differs in that a method for the purification of an other protein is claimed.

The problem to be solved by present claim 1 may therefore be regarded as the provision of a method for the purification of a protein.

The solution proposed, namely the provision of a method for the purification of an EGFR family derived protein (such as HER-2) cannot be considered as involving an inventive step for the following reasons:

In view of the disclosure in document D1, the skilled person would regard it as obvious to combine several purification methods, such as those disclosed in D1 for the purification of HER-2. The skilled person would proceed without the use of inventive skill, using common knowledge and routine only, with a reasonable expectation of success.

In conclusion, the subject-matter of claim 1 does not involve an inventive step. The subject matter of claims 2-33 does not seem to add subject matter that would render this part of the application inventive. Therefore, the subject matter of claims 1-33 does not satisfy the criterion set forth in Article 33(3) PCT.

- b) The identification of a suitable purification scheme is an elaborate process which requires a lot of experimentation before a useful set of steps are found for the particular protein and raw material in question. Finding an advantageous combination of methods amongst a large number of possibilities is certainly time consuming.
 - However, the method as claimed is a normal combination of standard techniques, that the person skilled in the art would consider. There does at present not appear to be a surprising effect linked to the specific combination. In conclusion, no inventive step can be acknowledged at present.
 - If <u>surprising effects</u> were linked to the method for the purification of a <u>specific</u> <u>protein</u>, as might be shown by <u>comparative examples</u>, the objection might be reconsidered.

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3. a) Document D2, which is considered to represent the most relevant state of the art for this part of the application, discloses (abstract; SEQ ID NO:3, 4; Figure 8) a Her-2 fusion protein, having a immunostimulatory effect. From this, the subject-matter of claim 34 differs in that a different HER-2 variant is claimed. SEQ ID NO:4 has 94.8% identity in a 660 amino acid overlap (33-692:20-674) with present SEQ ID NO:2.

The problem to be solved by present claim 34 may therefore be regarded as the provision of a HER-2 variant.

The solution proposed, namely the provision of a further HER-2 variant as defined by SEQ ID NO:2 cannot be considered as involving an inventive step for the following reasons:

In view of the disclosure in document D2, the skilled person would regard it as obvious to provide further variants of said protein. The skilled person would proceed without the use of inventive skill, using common knowledge only, with a reasonable expectation of success.

In conclusion, in the absence of a surprising effect, the subject-matter of claim 34 does not involve an inventive step. The subject matter of claims 35-48 does not seem to add subject matter that would render this part of the invention inventive. Therefore, the subject matter of claims 33-48 does not satisfy the criterion set forth in Article 33(3) PCT.

b) An inventive step for the claimed protein might be acknowledged if the protein imparted unexpected properties, such as the combination of superior stability, immunogenicity, 3D structure and induction of high quality antibody, when compared to other Her-2 fusions. However, no evidence for such unexpected properties was submitted.